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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,887	10/12/2005	Villoo Morawala Patell	20049.1USWO	4453
52835	7590	09/18/2007	EXAMINER	
HAMRE, SCHUMANN, MUELLER & LARSON, P.C.			KUMAR, VINOD	
P.O. BOX 2902			ART UNIT	PAPER NUMBER
MINNEAPOLIS, MN 55402-0902			1638	
			MAIL DATE	DELIVERY MODE
			09/18/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/552,887

Applicant(s)

PATELL, VILLOO MORAWALA

Examiner

Vinod Kumar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 17-28 is/are pending in the application.
- 4a) Of the above claim(s) 21, 22, 27 and 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-20, 23-25, and 26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 05/03/06; 02/08/07.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Election/Restriction***

1. Applicant's election with traverse of Group I, claims 17-20, and 23-26 in the paper filed July 2, 2007 is acknowledged.

Applicants argue that claims 21-22, and 27-28 of Group II are linked with the method of Group I, and thus inventions of Groups I and II must be examined together (response, page 1, lines 1-8 of 2<sup>nd</sup> paragraph).

Applicant's arguments were fully considered but were not found to be persuasive. It is maintained that restriction requirement is proper because the technical feature linking the inventions of Groups I-II does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art teachings of Tanaka et al. See the Office action mailed on May 31, 2007.

It is also important to note that invention of Group II is directed to a method of conferring increased tolerance to environmental stress in a rice plant cell using MnSOD gene product targeted to any plant cell organelle, whereas the invention of Group I requires that SOD gene product is targeted to only plastids. The inventions of Groups I and II also encompass different method steps.

Claims 21-22, and 27-28 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on July 2, 2007.

Accordingly, claims 17-20, and 23-26 of elected Group I are examined in this Office action. This restriction is made FINAL.

This application contains claims 21-22, and 27-28 drawn to inventions nonelected with traverse in the reply filed on July 2, 2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Information Disclosure Statement***

2. Initialed and dated copies of Applicant's IDS form 1449 filed 05/03/06 and 02/08/07 are attached to the instant Office action.

### ***Specification***

The disclosure is objected to because of the following informalities:

3. The abstract of disclosure is objected to because of the following informalities:  
Lines 2-3 of abstract do not read properly. In particular, the recitations "is

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ravages", and "ain" in line 2, and "wherewithal" in line 3 appear to have been misspelled and/or incorrectly cited. This is not proper language and should be corrected to reflect the claimed invention.

4. The brief descriptions to Figures 1-3 are missing in the specification. Also a brief description of Figure 1 should refer parts 1a, 1b, and 1c. Likewise, a brief description of Figure 2 should refer parts 2a and 2b. Similarly, a brief description of Figure 3 should refer parts (a), (b), and (c). See 37 CFR 1.74.

Appropriate action is required.

### ***Drawings***

The drawings are objected to because of the following informalities:

5. Drawings are objected to because they fail to comply with 37CFR 1.83.

Figures 1-3 fail to comply with 37 CFR 1.84(g) because these figures are framed.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the

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renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Appropriate corrections are required.

### ***Claim Objections***

6. Claims 17-20, and 23-26 are objected to because of following informalities:

Claim 17, line 1 recite "varieties" which should be singular to grammatically correspond to "a transgenic indica rice" which is singular.

Claim 17, part (a) recites "a transit peptide" in line 4, which is improper because a peptide cannot be a part of an expression vector which is made up of nucleotides. It is suggested to insert --coding sequence-- after "transit peptide" in line 4.

Claim 17, part (b), recites "transformant" which is improper because a cell becomes transformant when a vector is transferred into said cell. It is suggested to replace "transformant" with a --cell to produce a transformant--.

Claim 17, is objected for having improper article "the" before plant tissue in part (c). It is suggested to replace "the plant tissue" with --a plant tissue of said indica rice variety--.

In claim 17, part (d), insert --plant-- after "transformed" and before "tissue". Also insert --of said indica rice variety-- at the end of claim.

In claim 18, the recitation "is a Pea ribulose-1-5-bisphosphate carboxylase gene" does not read properly. It is suggested to replace the recitation with --is a pea ribulose-1-5-bisphosphate carboxylase transit peptide--, or --is encoded by a pea ribulose-1-5-bisphosphate carboxylase gene--.

Claim 19 is objected for misspelling "CvMV". It is suggested to replace "CvMV" with --CaMV--.

Claim 20 is objected for having improper article before "terminator" in line 1. It is suggested to replace "the" with --a--.

Claim 20 is objected for having improper article before "NOS" in line 1. It is suggested to replace "the" with --a--.

In claim 23, it is suggested to replace "that" in line 1 with --wherein the transgenic rice variety--.

Claim 24 is objected for reciting "specifically" which appears to be unnecessary. Also it is suggested that the varieties "Godavari 8" and "Salween 2" must be recited as the members of a "Markush Group" because the claimed rice variety can be either "Godavari 8" or "Salween 2".

In claims 25 and 26 are objected for having improper article "the" before "shelf life" in line 3. It is suggested to replace "the shelf life of rice" in line 3 with --a shelf life of said rice variety--.

Applicant is advised that should claim 25 be found allowable, claim 26 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both

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cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). In the instant case, claims 25 and 26 share the same scope and encompass the same method step to produce the same product.

Appropriate action/ corrections are required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 17-20, and 23-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 17 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in their recitation "gene" which is confusing since the limitation "gene" implies that the structure comprises the coding sequence and the associated promoter, terminator and enhancer encoding regions are also a part of the structure (see The Federal Register, Vol. 66, No. 4, Friday, January 5, 2001 at page 1108, left column, Endnote 13). In the instant case, Applicants do not appear to describe such "gene" associated nucleic acid sequences. It is suggested that "gene" be amended to --coding sequence-- in claim 17. For claim 18, see claim objections.

Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in its recitation "comprises a promoter, a superoxide dismutase (SOD) gene derived from *Nicotiana plumbaginifolia* L., and a transit peptide", which is confusing since it is



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unclear how "a transit peptide" made up of amino acids can be a part of the expression vector which is made up of nucleotide sequence. It is also unclear whether "promoter", "superoxide dismutase" and "transit peptide" are operably linked.

Claims 25 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in their recitation "significant role" in line 3 because the term "significant" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The metes and bounds of the recitation "significant" are unclear as they not defined.

Claims 23 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in their recitation "high" in line 1 of claim 23, and line 2 of claim 24 because the term "high" is a relative term which render these claims indefinite. The term "high" is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The metes and bounds of the recitation "high" are unclear as they not defined. The recitation lacks a comparative basis with a transgenic indica rice variety not comprising the expression vector.

Claims 25 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in their recitation "increased" in lines 1 and 2, and "increasing" in line 3 because the term "increased" or "increasing" is a relative term which render these claims indefinite. The term "increased" or "increasing" is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one

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of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The metes and bounds of the recitation "increased" or "increasing" are unclear as they not defined. The recitation lacks a comparative basis with a transgenic indica rice variety not comprising the expression vector.

Appropriate action is required.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 17-20, and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bowler et al. (European Patent Publication No. EP 0359617A2, Published March 21, 1990, Applicant's IDS) in view of Tanaka et al. (Plant Science, 148:131-138, 1999).

Claims are broadly drawn to a method for producing a transgenic indica rice variety comprising transformation of said variety with a construct which comprises a promoter, SOD gene derived from *Nicotiana plumbaginifolia*, and a transit peptide, or wherein said transit peptide is derived from pea ribulose-1-5-bisphosphate carboxylase gene, or wherein said promoter is a CaMV promoter, or wherein said construct further comprises a NOS terminator, or wherein said transgenic rice variety produces high levels of superoxide dismutase (SOD), or wherein said variety is Godavari 8 and

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Salween 2 which produces high levels of SOD, or wherein said transgenic plants confer increased yield under environmental stress conditions, or increased tolerance to pathogen attack and play a significant role in the food industry by increasing the shelf life of rice.

Bowler et al. teach a method of making a transgenic plant cell of *Nicotiana plumbaginifolia* with increased superoxide dismutase production, comprising transformation of said plant cell with a DNA construct, which comprises a 35 S CaMV promoter, operably linked with a nucleotide sequence encoding a superoxide dismutase derived from *Nicotiana plumbaginifolia* L., and wherein, the 5' end of said superoxide dismutase coding sequence is operably linked with a nucleotide sequence encoding a pea ribulose-1-5-bisphosphate carboxylase transit peptide sequence, and wherein the 3' end of said superoxide dismutase gene is further operably linked to a NOS terminator. The transgenic plant cells were regenerated to obtain a mature transgenic plant comprising said DNA construct. The transgenic plants also exhibited higher levels of superoxide dismutase production. The reference further teaches that said transgenic plants also exhibited increased tolerance to environmental stresses. The reference also teaches that increased SOD production in a plant cell results in increased resistance to pathogen attack. See in particular, page 2, lines 1-35; page 3, lines 50-60; page 4, lines 20-38, lines 63-65; page 5, lines 1-59; page 6, lines 5-24 and 39-59; page 8, line 61 to line 50 of page 10; page 11, lines 5-15; page 12, line 1 to page 13, line 45; page 16, line 49 to page 17, line 15.

Bowler et al. do not teach transformation of a rice plant with a chloroplast targeted SOD coding sequence.

Tanaka et al. teach making a transgenic plant cell of rice with increased superoxide dismutase production, comprising transformation of said plant cell with a DNA construct, comprising a 35 S CaMV promoter operably linked with a SOD coding sequence which is operably linked with a NOS terminator. The 5' end of the SOD coding sequence is operably linked with a nucleotide sequence encoding a chloroplast transit peptide signal. The transgenic plant cells are regenerated to obtain a mature transgenic plant of rice comprising said DNA construct. The transgenic plants also exhibited higher levels of superoxide dismutase production. The reference further teaches that said transgenic plants also exhibited increased tolerance to environmental stresses, and displayed higher yield under said environmental stress conditions. See in particular, page 131, abstract; page 132, materials and methods; page 134, figure 3; page 135, figures 4-6; page 136, figure 7.

At the time the invention was made, it would have been prima facie obvious to one of ordinary skill in the art to modify the method of making a stress-tolerant transgenic plant as taught by Bowler et al., by transforming any cultivated rice variety including an environmentally stress (salt) sensitive indica rice variety with Bowler et al. DNA construct to obtain the transgenic indica rice variety expressing a nucleic acid sequence encoding the SOD protein.

Given that Bowler et al. teach that SOD gene expression in plastids increases environmental stress tolerance in the transgenic plant, one of ordinary skill in the art

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would have been motivated to express DNA construct of Bowler et al. in any stress sensitive variety of rice including salt sensitive indica rice varieties to obtain the environmental stress tolerant transgenic plants with reasonable expectation of success.

Given that over production of SOD in a plant cell results in increased resistance towards pathogen attack as taught by Bowler et al., it would have been obvious to expect that said transgenic rice variety with increased SOD levels would have exhibited increased resistance to pathogen attack with reasonable expectation of success.

Obviously, said environmental stress tolerant transgenic rice variety would have exhibited increased shelf life and improved (higher) yield under environmental stress conditions, compared to a non-transformed control plant.

Thus, the claimed invention as a whole is prima facie obvious over the combined teachings of the prior art.

### ***Conclusions***

9. Claims 17-20, and 23-26 are rejected.

### ***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vinod Kumar whose telephone number is (571) 272-4445. The examiner can normally be reached on 8.30 a.m. to 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)272-0975. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/ Anne Marie Grunberg /